

## Food and Drug Administration, HHS

## § 172.5

172.712 1,3-Butylene glycol.  
172.715 Calcium lignosulfonate.  
172.720 Calcium lactobionate.  
172.723 Epoxidized soybean oil.  
172.725 Gibberellic acid and its potassium salt.  
172.730 Potassium bromate.  
172.735 Glycerol ester of rosin.  
172.736 Glycerides and polyglycides of hydrogenated vegetable oils.  
172.755 Stearyl monoglyceridyl citrate.  
172.765 Succistearin (stearoyl propylene glycol hydrogen succinate).  
172.770 Ethylene oxide polymer.  
172.775 Methacrylic acid-divinylbenzene copolymer.  
172.780 Acacia (gum arabic).  
172.785 *Listeria*-specific bacteriophage preparation.

### Subpart I—Multipurpose Additives

172.800 Acesulfame potassium.  
172.802 Acetone peroxides.  
172.804 Aspartame.  
172.806 Azodicarbonamide.  
172.808 Copolymer condensates of ethylene oxide and propylene oxide.  
172.809 Curdlan.  
172.810 Dioctyl sodium sulfosuccinate.  
172.811 Glyceryl tristearate.  
172.812 Glycine.  
172.814 Hydroxylated lecithin.  
172.816 Methyl glucoside-coconut oil ester.  
172.818 Oxystearin.  
172.820 Polyethylene glycol (mean molecular weight 200–9,500).  
172.822 Sodium lauryl sulfate.  
172.824 Sodium mono- and dimethyl naphthalene sulfonates.  
172.826 Sodium stearyl fumarate.  
172.828 Acetylated monoglycerides.  
172.829 Neotame.  
172.830 Succinylated monoglycerides.  
172.831 Sucralose.  
172.832 Monoglyceride citrate.  
172.833 Sucrose acetate isobutyrate (SAIB).  
172.834 Ethoxylated mono- and diglycerides.  
172.836 Polysorbate 60.  
172.838 Polysorbate 65.  
172.840 Polysorbate 80.  
172.841 Polydextrose.  
172.842 Sorbitan monostearate.  
172.844 Calcium stearyl-2-lactylate.  
172.846 Sodium stearyl lactylate.  
172.848 Lactylic esters of fatty acids.  
172.850 Lactylated fatty acid esters of glycerol and propylene glycol.  
172.852 Glyceryl-lacto esters of fatty acids.  
172.854 Polyglycerol esters of fatty acids.  
172.856 Propylene glycol mono- and diesters of fats and fatty acids.  
172.858 Propylene glycol alginate.  
172.859 Sucrose fatty acid esters.  
172.860 Fatty acids.  
172.861 Cocoa butter substitute from coconut oil, palm kernel oil, or both oils.

172.862 Oleic acid derived from tall oil fatty acids.  
172.863 Salts of fatty acids.  
172.864 Synthetic fatty alcohols.  
172.866 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.  
172.867 Olestra.  
172.868 Ethyl cellulose.  
172.869 Sucrose oligoesters.  
172.870 Hydroxypropyl cellulose.  
172.872 Methyl ethyl cellulose.  
172.874 Hydroxypropyl methylcellulose.  
172.876 Castor oil.  
172.878 White mineral oil.  
172.880 Petrolatum.  
172.882 Synthetic isoparaffinic petroleum hydrocarbons.  
172.884 Odorless light petroleum hydrocarbons.  
172.886 Petroleum wax.  
172.888 Synthetic petroleum wax.  
172.890 Rice bran wax.  
172.892 Food starch-modified.  
172.894 Modified cottonseed products intended for human consumption.  
172.896 Dried yeasts.  
172.898 Bakers yeast glycan.

AUTHORITY: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

SOURCE: 42 FR 14491, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 172 appear at 61 FR 14482, Apr. 2, 1996, 66 FR 56035, Nov. 6, 2001, 66 FR 66742, Dec. 27, 2001, 68 FR 15355, Mar. 31, 2003, 70 FR 40880, July 15, 2005, 70 FR 67651, Nov. 8, 2005, and 70 FR 72074, Dec. 1, 2005.

### Subpart A—General Provisions

#### § 172.5 General provisions for direct food additives.

(a) Regulations prescribing conditions under which food additive substances may be safely used predicate usage under conditions of good manufacturing practice. For the purposes of this part, good manufacturing practice shall be defined to include the following restrictions.

(1) The quantity of the substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect in food.

(2) Any substance intended for use in or on food is of appropriate food grade and is prepared and handled as a food ingredient.

(b) The existence of a regulation prescribing safe conditions of use for a food additive shall not be construed to

## § 172.105

relieve the use of the substance from compliance with any other provision of the Act.

(c) The existence of any regulation prescribing safe conditions of use for a nutrient substance does not constitute a finding that the substance is useful or required as a supplement to the diet of humans.

### Subpart B—Food Preservatives

#### § 172.105 Anoxomer.

Anoxomer as identified in this section may be safely used in accordance with the following conditions:

(a) Anoxomer is 1,4-benzenediol, 2-(1,1-dimethylethyl)-polymer with diethenylbenzene, 4-(1,1-dimethylethyl)phenol, 4-methoxyphenol, 4,4'-(1-methylethylidene)bis(phenol) and 4-methylphenol (CAS Reg. No. 60837-57-2) prepared by condensation polymerization of divinylbenzene (*m*- and *p*-) with *tert*-butylhydroquinone, *tert*-butylphenol, hydroxyanisole, *p*-cresol and 4,4'-isopropylidenediphenol.

(b) The polymeric antioxidant meets the following specifications:

(1) Polymer, not less than 98.0 percent as determined by an ultraviolet method entitled "Ultraviolet Assay," 1982, which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(2) Molecular weight: Total monomers, dimers and trimers below 500 not more than 1 percent as determined by a method entitled "Low Molecular Weight Anoxomer Analysis," 1982, which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call

## 21 CFR Ch. I (4-1-14 Edition)

202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(3) Phenol content: Not less than 3.2 milliequivalent/gram and not more than 3.8 milliequivalent/gram as determined by a method entitled "Total Phenols," 1982, which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(4) Heavy metals as lead (as Pb), not more than 10 parts per million. Arsenic (as As), not more than 3 parts per million. Mercury (as Hg), not more than 1 part per million.

(c) Anoxomer may be safely used as an antioxidant in food at a level of not more than 5,000 parts per million based on fat and oil content of the food.

[48 FR 18798, Apr. 26, 1983, as amended at 54 FR 24896, June 12, 1989]

#### § 172.110 BHA.

The food additive BHA (butylated hydroxyanisole) alone or in combination with other antioxidants permitted in food for human consumption in this subpart B may be safely used in or on specified foods, as follows:

(a) The BHA meets the following specification:

Assay (total BHA), 98.5 percent minimum.  
Melting point 48 °C minimum.

(b) The BHA is used alone or in combination with BHT, as an antioxidant in foods, as follows:

Food	Limitations (total BHA and BHT) parts per million
Dehydrated potato shreds .....	50
Active dry yeast .....	1,000
Beverages and desserts prepared from dry mixes .....	12
Dry breakfast cereals .....	50
Dry diced glazed fruit .....	132
Dry mixes for beverages and desserts .....	190
Emulsion stabilizers for shortenings .....	200